

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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KERRY LANGSTAFF, et al.,

Petitioners,

vs.

ALLEN A. MITCHELL, M.D.,  
SAMUEL M. LESKO, M.D., and  
TRUSTEES OF BOSTON UNIVERSITY,

Respondents.

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Civil Action No. 04-cv-11586-GAO

RESPONDENTS' OPPOSITION TO  
LANGSTAFF PLAINTIFFS'  
MOTION FOR RECONSIDERATION

Respondents Allen A. Mitchell, Samuel M. Lesko, and Trustees of Boston University (collectively "Respondents" or "Boston University") submit the following opposition to Petitioners' ("Langstaff Plaintiffs") Motion for Reconsideration. Langstaff Plaintiffs request this Court to vacate and reverse its order of June 29, 2004, in which the Court granted Boston University's Motion to Quash and denied Langstaff Plaintiffs' Motion to Compel.

Langstaff Plaintiffs have failed to fulfill the criteria to alter or amend a judgment as set forth in cases construing Fed. R. Civ. P. 59. They have failed to show a manifest error of law or to present newly discovered evidence, nor have they shown that there were facts or legal issues that were overlooked by the Court in its decision. Federal Deposit Ins. Corp. v. World Univ., Inc., 978 F.2d 10, 16 (1st Cir. 1992). Langstaff Plaintiffs' arguments for reconsideration are substantially the same as those that were presented to this Court at the time of the hearing on the

parties' discovery motions, and the Court found those arguments unpersuasive. For the reasons set forth below, Langstaff Plaintiffs' Motion for Reconsideration should be denied.

I. THE RULE 59(E) STANDARD TO ALTER OR AMEND A JUDGMENT IS STRINGENT AND SUCH MOTIONS SHOULD BE GRANTED SPARINGLY.

"A motion for reconsideration . . . is treated as a motion under Rule 59(e) of the Federal Rules of Civil Procedure." Trabal Hernandez v. Sealand Services, Inc., 230 F. Supp. 2d 258, 259 (D.P.R. 2002). "Motions under Rule 59(e) must either clearly establish a manifest error of law or must present newly discovered evidence." Bogosian v. Woloohojian Realty Corp., 323 F.3d 55, 72 (1st Cir. 2003) (quoting Jorge Rivera Surillo, Inc. & Co. v. Falconer Glass Indus., Inc., 37 F.3d 25, 29 (1st Cir. 1994)). Such motions should not be used to "raise arguments which could, and should, have been made before judgment issued." Id. See also Aybar v. Crispin-Reyes, 118 F.3d 10, 16 (1st Cir. 1997). Neither should such motions be used "to repeat old arguments previously considered and rejected. . . ." Nat'l Metal Finishing Co. v. BarclaysAmerican/Commercial, Inc., 899 F.2d 119, 123 (1st Cir. 1990).<sup>1</sup>

Motions for reconsideration "will generally be denied unless the moving party can point to controlling decisions or data that the Court overlooked . . . [and] that might reasonably be expected to alter the conclusion reached by court." Shrader v. CSX Transp., Inc., 70 F.3d 255, 257 (2d Cir. 1995). See also Rivera v. Doctor Susoni Hospital, Inc., 2004 WL 1494548 (D.P.R. June 24, 2004).

Given these stringent standards, it is not surprising that "motions for reconsideration are extraordinary remedies which should be used sparingly and are typically denied." Trabal

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<sup>1</sup> To this end, Respondents would point out that much of the text on pp. 5-6 and pp. 13-14 of Langstaff Plaintiffs' Motion for Reconsideration is taken verbatim from their Memorandum in Support of Response to Petitioners' Motion to Quash, filed on May 20, 2004.

Hernandez, 230 F. Supp. 2d at 259 (citations omitted). See also Medley v. Westpoint Stevens, Inc., 162 F.R.D. 697, 698 (M.D. Ala. 1995) (noting that Rule 59(e) motion “is an extreme measure”).

“A Rule 59(e) motion is addressed to the discretion of the district court,” and the discretion allowed to that court is “substantial.” Appeal of Sun Pipe Line Co., 831 F.2d 22, 25 (1st Cir. 1987), cert. denied, 108 S.Ct. 2821 (1988); Earnhardt v. Commw. of Puerto Rico, 744 F.2d 1, 3 (1st Cir. 1984); Robinson v. Watts Detective Agency, 685 F.2d 729, 743 (1st Cir. 1982), cert. denied, 103 S.Ct. 728 (1983). The denial of a motion for reconsideration is reviewed for manifest abuse of discretion. Jorge Rivera Surillo & Co., 37 F.3d at 27; Mackin v. City of Boston, 969 F.2d 1273, 1279 (1st Cir. 1992). See also White v. Fair, 289 F.3d 1, 10 (1st Cir. 2002).

II. LANGSTAFF PLAINTIFFS HAVE FAILED TO SHOW A MANIFEST ERROR OF LAW IN THIS COURT’S INTERPRETATION OF FED. R. CIV. P. 45(c)(3)(B)(ii) OR IN THE APPLICATION OF THE COURT’S DISCRETION UNDER RULE 45.

“In order to prevail on a Rule 59(e) motion based on manifest error of law or fact, the moving party must make a showing of some substantial reason that the court is in error.”

Kalman v. Berlyn Corp., 706 F. Supp. 970, 974 (D. Mass. 1989).

Plaintiffs have not argued that this Court erred in holding that Respondents’ Motion to Quash is properly considered under Rule 45(c)(3)(B)(ii) standards governing subpoenas that require disclosure of an unretained expert’s opinion or information. Indeed, as the Court noted in its Order of June 29, 2004: “Cases construing and applying the rule are sparse, and there is no authoritative interpretation binding in this circuit.” Order, at p. 4. Given the dearth of caselaw on this issue, there can be no basis for an argument under Rule 59(e) that the Court’s decision to

analyze Respondents' Motion to Quash under Rule 45(c)(3)(B)(ii) reflects a "manifest error of law."

When an unretained expert moves to quash a subpoena under Rule 45(c)(3)(B)(ii), the court is directed to consider whether the "party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship. . . ." Rule 45(c)(3)(B)(ii). "District courts exercise broad discretion to manage discovery matters." Heidelberg Americas, Inc. v. Tokyo Kikai Seisakusho, Ltd., 333 F.3d 38, 41 (1st Cir. 2003). Therefore, under Rule 45(c)(3)(B)(ii), determination of "substantial need" and "undue hardship" are questions that "[address themselves] to the sound discretion of the District Court in the first instance." Buchanan v. American Motors Corp., 697 F.2d 151, 152 (6th Cir. 1983); Kaufman v. Edelstein, 539 F.2d 811, 822 (2d Cir. 1976). A district court's discovery rulings are reviewed for abuse of discretion, United States v. Concemi, 957 F.2d 942, 949 (1st Cir. 1992), and will be overturned only "upon a clear showing of manifest injustice, that is where the lower court's discovery order was plainly wrong and resulted in substantial prejudice to the aggrieved party." Heidelberg Americas Inc., 333 F.3d at 41 (citations omitted).

Because discovery rulings under Rule 45 are addressed to the discretion of the district court, in order to show "manifest error of law" under Rule 59(e), Langstaff Plaintiffs must show that, as a matter of law, the Court abused its discretion when ruling (a) that Langstaff Plaintiffs had failed to demonstrate substantial need for expert testimony; and (b) that discovery of non-expert evidence would impose an undue burden on Respondents under Rule 45(c)(3)(A)(iv). Langstaff Plaintiffs cannot show such an abuse of discretion.

Langstaff Plaintiffs suggest that because discovery under Rule 45 is generally allowed for all relevant non-privileged material, denial of discovery under Rule 45 should be exceedingly

rare. See Mot. for Recons., at pp. 6-7. However, there are many cases in which courts have found that parties who have subpoenaed evidence from unretained third-party experts have failed to make the requisite showing of substantial need sufficient to outweigh the burdens imposed upon the expert. See, for example, Dow Chemical Co. v. Allen, 672 F.2d 1262, 1272 (7th Cir. 1982) (need for information not compelling under the circumstances); Buchanan, 697 F.2d at 152 (quashing subpoena because too burdensome to have expert explain raw data underlying his research); Biotechnology General Corp. v. Novo Nordisk A/S, 2003 WL 21057238 (D. Del. May 7, 2003) (finding that plaintiff has not demonstrated a substantial need that could not be otherwise met without undue hardship); Schering Corp. v. Amgen, Inc., 1998 WL 552944 (D. Del. Aug. 4, 1998) (plaintiff did not meet burden of showing substantial need for testimony); Wright v. Jeep Corp., 547 F. Supp. 871 (E.D. Mich. 1982); In re Snyder, 115 F.R.D. 211, 216 (D. Ariz. 1987) (finding that “[o]ppportunity enough exists [in the judicial process] for an adversarial exploration of truth in litigation without the necessity of conscripting non-witness researchers into discovery and trial appearances”).

Indeed, even in the case of Anker v. G.D. Searle & Co., 126 F.R.D. 515, 518 (M.D.N.C. 1989), which Langstaff Plaintiffs cite for the proposition that this Court should be “cautious in restricting discovery,” the court denied plaintiffs’ subpoena for documents and expert testimony of a researcher. The Anker court found that, although the researcher was not per se protected from third party discovery, the requesting party had failed to show that the relevance and need for the evidence outweighed the burden and prejudice to the non-party expert. Id., at 521. As in this case, the Anker court also found that plaintiffs had not demonstrated that the expert’s opinion was relevant to the controversy in the underlying case. Id.

Because Langstaff Plaintiffs cannot show a manifest error of law in the form of per se abuse of discretion, their Motion under Rule 59(e) must fail.

III. LANGSTAFF PLAINTIFFS HAVE NOT PRESENTED THE COURT WITH ADDITIONAL EVIDENCE THAT WAS NOT PREVIOUSLY AVAILABLE WHEN THE HEARING ON THIS MATTER WAS HELD.

If a movant is claiming newly discovered evidence as the basis for a motion under Rule 59(e), “the movant must demonstrate that the evidence was in existence at the time of the trial, but that the moving party was excusably ignorant.” Kalman, 706 F. Supp. at 974 (citation omitted). The district court judge has “substantial discretion in deciding whether to . . . allow the losing party to argue new material. . . .” Appeal of Sun Pipe Line, 831 F.2d at 25. Here, Langstaff Plaintiffs have failed to present any new evidence of which they were excusably ignorant at the time of the hearing on this discovery matter.

A. Dr. Anthony Temple’s Deposition and Dr. Michael Nicar’s Expert Report Do Not Constitute “Newly Discovered Evidence.”

Langstaff Plaintiffs seek to present “new evidence” to the Court in the form of the full transcript of Dr. Anthony’s two-day deposition, see Mot. for Recons., Ex. A., and the expert report of Dr. Michael Nicar, id., Ex. H.<sup>2</sup> Dr. Temple is employed by McNeil Consumer & Specialty Pharmaceuticals (“McNeil”) as Vice President of Medical Affairs. Dr. Nicar has been retained by Langstaff Plaintiffs as a toxicology expert.

Dr. Temple’s deposition was completed on May 19 and 20, 2004, a full three weeks before this Court’s June 10, 2004, hearing on Respondents’ Motion to Quash and Langstaff Plaintiffs’ Motion to Compel. Because Dr. Temple’s deposition was videotaped, an immediate

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<sup>2</sup> While Langstaff Plaintiffs claim that the other seventeen Exhibits attached to their Motion constitute “additional evidence,” they do not appear to contend that this evidence is newly discovered. See Mot. for Recons., at p. 7. To the extent Langstaff Plaintiffs present these documents in order to make arguments that were not made previously to the Court, this is not a valid basis for a Motion under Rule 59(e). See Federal Deposit Ins. Corp., 978 F.2d at 16.

record of the deposition was available on May 20, 2004. Even if Dr. Temple's deposition provided "new evidence" of which Langstaff Plaintiffs were unaware when responding to Boston University's Motion to Quash in May of 2004, Langstaff Plaintiffs had ample opportunity to present such evidence to the Court prior to the June 10 hearing on the discovery motions. Furthermore, transcripts of Dr. Temple's deposition were apparently available on June 7, 2004. Thus, even if it was not feasible for Langstaff Plaintiffs to provide a copy of the deposition videotape to the Court, copies of the transcripts could have been provided to the Court on or before the hearing on June 10, 2004. See Waltman v. International Paper Co., 875 F.2d 468, 474 (5th Cir. 1989) (finding that deposition transcript on which Rule 59 motion was based could have been presented to court prior to its initial ruling).

Dr. Nicar's expert report is dated June 16, 2004. While Langstaff Plaintiffs may not have had the written report containing Dr. Nicar's expert opinion until after the hearing on the discovery motions, all of the evidence on which Dr. Nicar relied in formulating his opinion was clearly available to Langstaff Plaintiffs at the time of the June 10 hearing. Moreover, as Dr. Nicar has not yet been accepted as an expert by the California Court in the underlying action, it is unclear whether his report, written pursuant to Rule 26(a)(2)(B), should even be considered "newly discovered evidence." See Webber v. Mefford, 43 F.3d 1340, 1345 (10th Cir. 1994) (declining to review new expert affidavit under Rule 59(e)).

- B. Even if this Court Finds that Dr. Temple's Deposition Constitutes New Evidence, Plaintiffs Have Failed to Show how Temple's Deposition Would Change the Court's Conclusions Regarding the Relevancy of the Evidence Sought from Drs. Lesko and Mitchell.

Langstaff Plaintiffs appear to argue that Dr. Temple's deposition testimony is relevant to the discovery dispute before this Court because it contains "inconsistencies" regarding the Boston University Fever Study (BUFS). They claim that there is information that they "need to

know” to clear up these inconsistencies and that such information can only be obtained from Drs. Mitchell and Lesko and Slone Epidemiology Center (“Slone”).

As an initial matter, many of the areas Langstaff Plaintiffs point to on pp. 7-12 of their Motion as requiring further exploration were already described during argument before this Court on June 10. Langstaff Plaintiffs reiterate that they wish to ascertain who determined final control over the structure of BUFS; whether pressure was exerted on Slone by McNeil to complete the study more quickly, what knowledge was reported by Slone to McNeil regarding incidences of skin reactions and when this was reported, whether McNeil recommended changes to the final report or the published article. However, as this Court noted in its earlier Order, “[t]he fact that the Langstaffs are curious about the answers to such questions only explains why they seek the discovery, not why they should be allowed to obtain it.” Order, at p. 8. Langstaff Plaintiffs have still not come up with any evidence of improper influence by McNeil over the study that would require further exploration through Drs. Lesko’s and Mitchell’s depositions. In the absence of such evidence, Plaintiffs cannot demonstrate a “substantial need” for further evidence that is sufficient to overcome the protections afforded by Rule 45 to unretained experts.

The bulk of the remaining areas that Langstaff Plaintiffs seek to explore appear to relate to impeachment of the validity of the study. For example, Langstaff Plaintiffs seek to determine, among other things, when and under what circumstances Dr. Lesko was “unblinded”; why emergency room records were not collected; whether tests were done to differentiate between different types of skin reactions; and what role Dr. Temple played on the advisory committee. See Mot. for Recons., at pp. 8-12. However, Langstaff Plaintiffs have again failed to articulate why “evidence tending to impeach the soundness of [the] study or its conclusions is . . . by itself, directly probative of tortuous behavior by McNeil. Order, at p. 8.



As noted by this Court, Plaintiffs' theory is that the FDA allowed a change to the warning label for over-the-counter ibuprofen based on McNeil's submission of BUFS, which they allege was a poorly conducted study that underreported the risk of skin reactions. However, as the Court recognized at oral argument, McNeil cannot be held liable on this theory unless it is shown (a) that McNeil was aware that BUFS was not a valid study; and (b) that McNeil nonetheless presented this study to the FDA in support of its new drug application. Plaintiffs have still not shown why further discovery from Lesko or Mitchell would advance this hypothesis, nor have they shown new evidence in support of this theory. Because Plaintiffs' purported "new evidence" would not affect the Court's conclusions, their Motion for Reconsideration should be denied. See Brinkman v. State of Kansas Dept. of Corrections, 869 F. Supp. 902, 905 (if purported new evidence would not affect court's previous ruling, Rule 59(e) motion must be denied).

C. Dr. Nicar's Expert Report Demonstrates that Langstaff Plaintiffs Are Perfectly Able to Attack the Conclusions and Methodology of the Fever Study Without Further Discovery from Boston University, Dr. Lesko or Dr. Mitchell.

Langstaff Plaintiffs state that "Drs. Mitchell and Lesko are unique witnesses" and "are the only source to answer [Langstaff Plaintiffs'] questions regarding the Boston University Fever Study." Mot. for Recons., p. 13. However, even without access to depositions of Drs. Mitchell or Lesko or documents held by Slone Epidemiology Center, Langstaff Plaintiffs' expert, Dr. Nicar, has already opined that "BUFS had serious design flaws," that "[t]he BUFS report to the FDA underestimated" serious skin-related side effects from ibuprofen, and that the study was "not sufficient for evaluation of the safety of ibuprofen in children being treated for fever, with respect to EM/SJS/TEN." See Mot. for Recons., Ex. H., pp. 13-17.

Dr. Nicar engages in an extensive critique of BUFS on pages 13-17 of his expert report. Not only did he have access to Dr. Lesko and Mitchell's published articles, but he apparently reviewed the entire BUFS data base, containing the records of all 80,000 study participants (see Ex. H, p. 14); interim reports made by Drs. Lesko and Mitchell to McNeil and provided to the FDA (id., at p. 15); pre-publication manuscripts submitted by Drs. Lesko and Mitchell to McNeil (id.); draft final reports of the study conclusions submitted by Drs. Lesko and Mitchell to McNeil (id., at p. 16); hospitalization records from patients enrolled in BUFS (id.); and volumes of documents submitted to the FDA including data listings for each patient (id., at p. 17).

At no point does Dr. Nicar indicate that he is unable to assess the methodology or conclusions of BUFS without further information that can be gained only through the depositions of Drs. Mitchell and Lesko. Nor does Dr. Nicar claim that the voluminous documents to which he has already had access are insufficient to allow him to properly assess and critique the study. In Anker v. G.D. Searle, plaintiffs' failure to make such a showing supported the Court's grant of a motion to quash a subpoena issued for an unretained expert's research papers. See Anker, 126 F.R.D. at 521. From Dr. Nicar's expert report, it would appear that Langstaff Plaintiffs have been able to critically examine and evaluate the Boston University Fever study without depositions of Drs. Lesko and Mitchell or further production of documents from Slone. This conclusion supports the Court's holding that Langstaff Plaintiffs have failed to met their burden of showing a substantial need for the doctors' testimony that would outweigh the significant burden that would be imposed on the doctors in responding to Langstaff Plaintiffs' discovery requests. Likewise, Langstaff Plaintiffs have not shown a sufficient need for documents that would justify the burdens their subpoenas duces tecum would impose on the custodians of record.

CONCLUSION

Petitioners have failed to fulfill the requirements for motions brought under Rule 59(e) in that they have not demonstrated that this Court's ruling was based on a manifest error of law or fact, nor have they set forth newly discovered evidence. As such, their Motion for Reconsideration should be denied.

Respectfully submitted,

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TRUSTEES OF BOSTON UNIVERSITY,  
By their attorney,

s/Erika Geetter

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